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TITLE: Breast Cancer Epidemiology in Puerto Rico

PRINCIPAL INVESTIGATOR: Cruz Nazario, Ph.D.

CONTRACTING ORGANIZATION: University of Puerto Rico
San Juan, PR 00936-5067

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14. ABSTRACT

This first year report provides evidence that the development of the infrastructure for the study of the Epidemiology of Breast Cancer and the pilot case-control study as well as the initiation of the training of investigators is undergoing as expected. The establishment of a mentor-mentee relationship as well as the communication venues has been successful. Weekly teleconference calls, frequent e-mails and individual telephone calls when needed have been the usual method of communication. The first steps of the case-control studies are underway (identification of key personnel and initial training in the study protocol, obtaining local IRBs and HIPAA approvals, designing the questionnaire, etc.). The first year of the award has been successful.

15. SUBJECT TERMS
Breast cancer; population-based study, epidemiology

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Annual Report, 01 June 1, 2007 – June 30, 2008
Breast Cancer Epidemiology in Puerto Rico
BCRP HBCU/MI Partnership Training Award BC060131
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Grants Officer's Representative: Theresa J. Miller, Ph.D.

INTRODUCTION:

This project has two mayor goals: to design and conduct a pilot case-control breast cancer study among Puerto Rican women and to train and develop researchers in breast cancer at the minority institution. The case control study will enroll women aged 30-79 who are residents of the San Juan metropolitan area. Cases will be women with incident, primary, pathologically confirmed breast cancer with no history of previous cancer other than non-melanoma skin cancer; controls will be frequency-matched by age and randomly selected from female residents of the same geographical area. We will examine adult and childhood factors in relation to risk of breast cancer in this understudied population of Puerto Rican women. The specific aims are: to examine dietary risk factors in relation to breast cancer and also in relation to tumor characteristics (e.g., estrogen and progesterone receptor status); to examine other established risk factors such as lifetime weight gain, physical activity, alcohol consumption, reproductive history among Puerto Ricans in relation to breast cancer risk; and to examine factors related to early life exposure including birth weight, adult height, childhood diet, physical activity, environmental factors and residential history as a proxy for environmental exposure in relation to proxy risk. The overall training goal is to develop a team of independent investigators with the necessary skills to develop a program of breast cancer research in PR and to obtain funds and support for that research. To accomplish this goal, researchers from the UPR will obtain formal training in cancer epidemiology and participate in the design and conduct of the population-based case control study.

BODY:

STATEMENT OF WORK

Task 1. Training researchers from the University of Puerto Rico

There are several goals for the training of investigators at the minority institution. They are: 1) to develop expertise in breast cancer epidemiology, especially in the areas of interest for the planned study, 2) to understand cutting edge developments in breast cancer in order to design the best possible study and 3) to develop needed expertise specially for the planned as well as for future studies. In order to meet the training goal, to develop expertise in breast cancer epidemiology, during the first period of the award, two of the investigators from the minority institution, Drs. Schelske-Santos and Mansilla-Rivera, participated in summer training. Dr. Schelske-Santos took two courses in Nutritional Epidemiology and Introduction to Obesity and Diabetes Epidemiology at Johns Hopkins Graduate Summer Institute. Both, diet and body size, are important elements of the planned study. Dr. Mansilla-Rivera took a course in Environmental Epidemiology at Ohio State University in order to better understand ascertainment and analysis of environmental exposure in relation to breast cancer. Also Dr. Mansilla-Rivera and Dr. Nazario took a course in Logistic Regression in Epidemiology at University of Puerto Rico, Medical Sciences Campus in May, 2008. Drs. Schelske-Santos and Nazario attended the AACR meeting in April 2008 and also met with investigators at University at Buffalo to discuss issues regarding implementation of the study protocol. Those activities were important for the second goal of understanding cutting edge science. Dr Schelske-Santos participated in the Women in Cancer Research conducted at AACR.
There were several activities for the training directly related to the planned study. Dr Nazario was trained in the use of a colorimeter for the measurement of sun exposure based on changes in skin color.

In addition, laboratory personnel from RPCI (Lisa Carter) and from University of Puerto Rico (Nilda González) met and coordinated their activities regarding biological specimen collection, processing and long term storage.

Task 2. Develop and maintain communications among participating investigators.

During the first year of the award, the minority and the mentoring institutions have been in close communication to develop the study protocol, and to develop the study questionnaire. This communication has included weekly teleconference calls of at least one hour, as well as frequent communications by email. Dr Freudenheim visited the University of Puerto Rico to meet with researchers and work on the questionnaire and on the development of the study protocol. During that visit, Drs. Freudenheim, Nazario, Schelske-Santos and Mansilla-Rivera trained the study interviewer. In addition, there was considerable discussion of the study protocol including ways to reduce interview bias. Emails have been frequently used to confirm meetings agreements and to submit written reports between the two institutions. Schelske-Santos, Nazario, and Hernández came to Buffalo to meet with laboratory personnel and to work on the questionnaire.
Schelske-Santos, Nazario, Mansilla-Rivera, and Freudenheim attended the AACR and the Era of Hope meetings. At those meetings, they reviewed progress toward implementation and discussed next steps.

Task 3. To design, implement and analyze a case control study of breast cancer in Puerto Rico.

The Principal Investigator met with Puerto Rico Central Cancer Registry Director to estimate expected number of Breast Cancer cases by hospitals within the San Juan Metropolitan Catchment area. The Project Coordinator has contacted the Oncology Hospital, which is located within the Medical Center Area, to identify sources of cases. The geographical area from which cases and controls will be drawn has been defined as the following municipalities: San Juan, Bayamón, Carolina, Guaynabo and Toa Baja. The list of potential population controls is available to identify eligible controls.

The survey instrument to be use in this study has been designed using other questionnaires that have already been tested and used in population-based cancer studies in Puerto Rico as well as new questions specific to our study. The questionnaire will collect information on diet, lifetime physical activity, smoking, sun exposure, demographic characteristics, personal and familial history of chronic diseases, residential history, vitamin and medications, menstrual, reproductive and weight history, cancer diagnosis and treatment, among others. The questionnaire for the early life diet was developed using food lists from nutrition studies conducted in Puerto Rico in the early 50s. The questionnaire will be tested on people with backgrounds similar to the target population to evaluate how it handles cultural and social sensitive issues, vocabulary, and questions' sequence. Results will be incorporated into the final instrument version (Appendix A, Draft questionnaire). The final version of the questionnaire will be translated into English so as to be used by bilingual or by English speaking Hispanics.

The study protocol (identification of incident cases at hospitals, identification of control and laboratory protocol for the collection and management of biological samples) has been designed. IRB documents were developed in Spanish and translated into English. Also, the Informed Consent was submitted to the appropriate IRB Committee in each institution: local IRB (University of Puerto Rico) and to the mentoring institutions (University at Buffalo, and Roswell Park Cancer Institute). The study protocol and Informed Consents were fully approved by the three IRB Committees. We will be submitting to all these documents to the Human Subjects Protection Scientist, all documents by the middle of July 2008, for their revision.

At this moment, no problems have been anticipated that could impede the progress of this project. Investigators will develop plans for the next several years for their training. They will participate in summer courses in epidemiology (basic and applied) courses. We anticipate that there will be IRB approval of the protocol the Human Subjects Protection Scientist. We plan to finalize the questionnaire, and to test it with using a formal interview format. We hope to begin interviewing in the next month. We have identified personnel for all stages of the study. Interviewers, nurses, laboratory personnel, and community outreach personnel from other studies will perform tasks related to interviewing, drawing blood and taking anthropometric measurements, as well as processing blood and saliva specimens. These individuals have been trained in this protocol.

KEY RESEARCH ACCOMPLISHMENTS:

- Establishment of collaboration links with Oncology Hospital Isaac Gonzalez Martínez (to identify sources of cases).
- Identification of Key personnel and completion of initial training.
- Training of study investigators in basic epidemiology and nutrition epidemiology (Appendix B and C).

REPORTABLE OUTCOMES:

- Survey instrument draft "CASE CONTROL STUDY OF BREAST CANCER IN PUERTO RICO" (Appendix A).
- Protocol study and Informed Consent fully approved in both institutions IRB Committee (Appendix D).
- Instrument for evaluating participant' eligibility (Appendix E).
- Poster session at Era of Hope meeting (Appendix F).

CONCLUSION:

This first year report provides evidence that the development of the infrastructure for the pilot case-control study and the initiation of the training of investigators is undergoing as expected. The establishment of a mentor-mentee relationship as well as the communication venues has been successful. The first steps of the case-control studies are underway (identification of key personnel and initial training in the study protocol, obtaining local IRBs and HIPAA approvals, designing the questionnaire, etc.).

REFERENCES: N/A

APPENDIX:

- Survey instrument draft "CASE CONTROL STUDY OF BREAST CANCER IN PUERTO RICO" (Appendix A).
- Training of study investigators in basic epidemiology and nutrition epidemiology (Appendix B and C).
- Protocol study and Informed Consent fully approved in both institutions IRB Committee (Appendix D).
- Instrument for evaluating participant' eligibility (Appendix E).
- Poster session at Era of Hope meeting (Appendix F).

30-Jun-08

PARTICIPANT'S CONTROL SHEET

CONFIDENTIAL
Control Number:

1	2	3	4	5	6

Name: _____
Last Name First Name Initial

Address: (1) _____

_____

Address: (2) _____

_____

Telephone Number: | | | | - | | | | - | | | | |

Other Tel. Number: | | | | - | | | | - | | | | |

Interview schedule:

DATE			HOUR	COMMENTS
Day	Month	Year		

DRAFT

Forma JHS-CMN CDMRP#BC060131
DRAFT

UNIVERSITY OF PUERTO RICO- RIO PIEDRAS
MEDICAL SCIENCES CAMPUS

CONTROL NUMBER

1	2	3	4	5	6

Atabey Study
For the health of women in Puerto Rico

CASE CONTROL STUDY OF BREAST CANCER IN PUERTO RICO

SURVEY

2008

SPONSORED BY: CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAM'S BREAST CANCER RESEARCH PROGRAM CDMRP #BC060131

STUDY INTRODUCTION

Read to participant

We are carrying out a study on women in Puerto Rico to learn about their health and the health of their family, including diet and level of exercise.

Your participation in this investigation is very important to us and your answers will enhance our knowledge about the health of women in Puerto Rico. We would like to count on your cooperation. Your participation is voluntary and all of the information provided will be kept in strict confidentiality.

If you agree to participate in this study, you will be required to carefully read and sign the document that contains the consent form. This document contains detailed information with the names and telephone numbers of the people leading this survey in case you need to ask any questions. Before beginning, it is important that you have signed the forms to evidence that you have accepted to participate in this study.

First we will take the blood sample, then we will take the body measurements and lastly we will be asking the survey questions. If you can not donate blood, a saliva sample can be also analyzed. After taking the blood or saliva sample and your body measurements, we will be performing an interview that will only take about 45 minutes approximately.

After completing this process, we will be providing a monetary incentive in appreciation of your cooperation.

(***At this point, the consent form is reviewed with the participant and signed.***)

I. Signed consent form? Yes _____ No _____

II. Blood sample Completed _____ Not completed _____

III. Body measurements

Height: _____ (inches) Weight: _____ (pounds, ounces)

Waist: _____ (inches) Hips: _____ (inches) Height sitting: _____ (inches)

iv. Skin tone (under arm): 1. _____ 2._____

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MEDICAL SCIENCES CAMPUS

SURVEY (DRAFT)

Code: ___ ____ ____	Date of interview ☐☐ ☐☐ ☐☐☐☐ Day Month Year
	Start time: ____ ____:___ ___ a.m.___ p.m.___

Part I. SOCIO-DEMOGRAPHIC INFORMATION

***Read to participant*:**

As I mentioned previously, the last part of the study will be questions in reference to you and your family's health and some additional questions about your diet and levels of exercise throughout your life. I can repeat the question as many times as you need in order for you to provide the best answer. First I would like to ask you …

1. What is your birth date? Date: ☐☐ ☐☐ ☐☐☐☐
   Day Month Year

2. Which one of the following options best defines your marital status? ☐
   - Married.....1
   - Living with partner, not married…….....2
   - Single….…….....3
   - Separated (not living with partner)…….....4
   - Divorced (not living with partner)…….....5
   - Widow (not living with partner)…….....6
   - Does not want to answer.……..…….…….. 9
   - Other.....7
     Describe: _____
     _____

3. What is the highest level or year of schooling that you completed? ☐☐
   - 00 Didn't go to school
   - 01-12 (**Code from 01=first grade until 12=grade 12th**)
   - 13 Technical or Vocational
   - 14 Associate Degree
   - 15 Bachelor's Degree
   - 16 Graduate Studies
   - 17 Other _____
   - 99 Does not want to answer / can't remember

We'd like to know a little about you and your mother at the time you were born.

4. Please tell me where your mother lived when you were born? (Please provide as much information as possible, if you know the complete address.)

a. Address and county or district: _____

_____

b. Municipality: _____c. Zip code: _____

d. How long did you live there after you were born? Months _____ Years _____

e. How much did you weigh at birth?_____ (pounds and ounces)

__ Less than 5 lbs.
__ Between 5 lbs. and 6 lbs.
__ Between 6.1 lbs. and 7 lbs.
__ Between 7.1 lbs. and 8 lbs.
__ Between 8.1 lbs. and 10 lbs.
__ More than 10 lbs.

[If the participant cannot remember the exact weight read the ***following alternatives to help her remember. Tell her: Please try to remember approximately***]

__ Can't remember the exact weight but I think it was:
__ Average, ___less than average (skinny), ___more than average (chubby)
__ Don't know

f. Were you breast fed (breasting) when you were born?

___ (0) No, ___ (1) Yes, How long? _____ months or years, ___ (9) Don't know

g. Did your mother suffer from high blood pressure or preeclampsia while she was pregnant with you?

___ (0) No, ___ (1) Yes ___ (9) Don't know

h. Did your mother suffer the death of a close relative while she was pregnant with you?

___ (0) No, ___ (1) Yes ___ (9) Don't know

Now I would like to know about your life as an adolescent, more or less when you were between 12 and 13 years old. Although some time has passed please try to remember about that time of your life when you were in middle school or sixth grade or seventh grade. Plea□se provide as much information as possible.

5. Where did you live when you were between 12 and 13 years old? (If you lived in more than one address, during those years, please give us the address where you lived the longest.)

a. Address or county or district _____

_____

b. Municipality: _____ c. Zip code: _____

d. How long did you live there? _____Months Years _____

6. Now we would like you to remember the foods that you consumed when you were 12-13 years old. Answer the best you can.

6 a. When you were 12-13 years old **you ate/ drank…?**	**6b. How frequent were you accustomed to eat/ drink…?**
Bread ☐ Yes (1) No (0), Jump to next item	(0) Rarely ☐ (1) Weekly (2) Daily
Hot cereal (Oatmeal, Cream of Wheat, etc) Yes (1) No (0), Jump to next	(0) Rarely (1) Weekly (2) Daily
Milk, included in the cereal Yes (1) No (0), Jump to next item	(0) Rarely (1) Weekly (2) Daily
Coffee with milk Yes (1) No (0), Jump to next item	(0) Rarely (1) Weekly (2) Daily
Fruits & Fruit Juices Yes (1) No (0), Jump to next item	(0) Rarely (1) Weekly (2) Daily
Eggs Yes (1) No (0), Jump to next item	(0) Rarely (1) Weekly (2) Daily
Rice Yes (1) No (0), Jump to next item	(0) Rarely (1) Weekly (2) Daily
Beans (kidney, red or pink) Yes (1) No (0), Jump to next item	(0) Rarely (1) Weekly (2) Daily
Chicken Yes (1) No (0), Jump to next item	(0) Rarely (1) Weekly (2) Daily
Steak, pork Yes (1) No (0), Jump to next item	(0) Rarely (1) Weekly (2) Daily
Bacon, ham, sausage Yes (1) No (0), Jump to next item	(0) Rarely (1) Weekly (2) Daily
Fish (Tuna, fried fish) Yes (1) No (0), Jump to next item	(0) Rarely (1) Weekly (2) Daily
Starchy vegetables (plantain, taro root, cassava) Yes (1) No (0), Jump to next item	(0) Rarely (1) Weekly (2) Daily
Salad (lettuce & tomatoes) Yes (1) No (0), Jump to next item	(0) Rarely (1) Weekly (2) Daily

6 a. When you were 12-13 years old **you ate/ drank…?**	**6b. How frequent were you accustomed to eat/ drink…?**
Vegetables Yes (1) ☐ No (0), Jump to next item	(0) Rarely (1) Weekly (2) Daily ☐
Sodas, light drinks Yes (1) No (0), Jump to next item	(0) Rarely (1) Weekly (2) Daily
Fried Foods (chips, fried plantain, arepas) Yes (1) No (0), Jump to next item	(0) Rarely (1) Weekly (2) Daily
Codfish salad (Serenata bacalao) Yes (1) No (0), Jump to next item	(0) Rarely (1) Weekly (2) Daily
Rice Stew (with chicken, shrimp or pigeon peas) Yes (1) No (0), Jump to next item	(0) Rarely (1) Weekly (2) Daily
Meat Stew Yes (1) No (0), Jump to next item	(0) Rarely (1) Weekly (2) Daily
Fast Food (Hamburger, Taco, fried chicken, French fries) Yes (1) No (0), Jump to next item	(0) Rarely (1) Weekly (2) Daily
Donuts, cake, cookies Yes (1) No (0), Jump to next item	(0) Rarely (1) Weekly (2) Daily
Ice Cream Yes (1) No (0), Jump to next item	(0) Rarely (1) Weekly (2) Daily

7. Where have you lived the most in your lifetime? (In which place did you live or have lived most of your adult life] (If you know the address please provide as much information as possible.)

a. Address, county or district: _____

_____

b. Municipality: _____c. Zip Code: _____

d. How long did you live there? Months _____ Years _____

e. Years lived at that address? _____ (years) or from 19_____ to _____

Interviewer: Code No, Don't Know or Yes. If the answer is Yes, ask with what frequency do you take them (every day or less) and the quantity (number of pills or units).

8a. Have you taken vitamins, minerals, or drugs during the last 12 months?
No ____ or Do not remember ___Jump to question 9.
Yes ____

8b. In the last 12 months have you taken any of the following: **Medicines, vitamins or minerals?**	**No (0) Don't know (9) Yes (1) →**	**Frequency**		**Quantity you take**	
		Every day (2)	**Sometimes (3)**	**# pills**	**Units (mg, µ, IU.)**
8a. Vitamin C					
8b. Vitamin A					
8c. Vitamin E					
8d. Vitamin D					
8e. Vitamin B12					
8f. Beta Carotene					
8g. Folic acid					
k. Calcium					
8l. Iron					
8m. Selenium					
8n. Zinc					
8n. Magnesium					
8h. Multi-vitamins: one a day					XX
8i. Multi-vitamins: Stress-tabs					XX
8j. Multi-vitamins: Therapeutics, Theragran					XX
8o. Aspirin (bufferin, ecotrin)					XX
8p. Ibuprofen (Motrin)					XX
8q. NSAIDS (naproxen, aleve, naprosyn, daypro, celebrex, vioxx, indocin, clinoril)					XX
8s. Antidepressives					XX
8t. Statins Drugs that lower cholesterol like atorvastatin (lipitor), fluvastin (lescol), rosuvastitin (crestor), pravastatin (pravachol), lovastatin (mevacor), simvastatin (zocor))					XX
8u. Others:					

8s. **Antibiotics**: Have you taken antibiotics for **six months or more for a condition**? ___yes ___ no

If you have taken them, When was the last time ___ ___ ___ ___ (Year)

How long? _____months _____years

For what reason did you take antibiotics? _____

Which one? (if you took more than 1 antibiotic, please indicate the one you used the longest time)
_____

Part II. Menstrual, reproductive and weight history

Read to participant

Now I will be asking you some questions about your menstruation and if you have been pregnant.

9. How old were you when you got your first menstruation (period)? ☐☐
(If they don't remember, please tell me the best you can recall
___ ____age doesn't remember (99)

10. Do you still get your menstruation?
____ Yes (go to 10a)
____ No (go to 11)
____ Is not sure, explain _____ go to 11

10a. When was your last menstrual period? (Please mention the first day and month)
Month _____ Day _____ year 20___ go to 14

11. Have you stopped menstruating completely or are you in menopause? This is if you haven't gotten your menstruation in the last 12 months (one year).
____ Yes (go to 11a)
____ No (go to 14)
____ Is not sure, explain _____ go to 14

11a. How old were you when your period stopped? _____ Age

11b. When did your menopause begin or your menstruation stop. What was the reason?
____ Surgery (hysterectomy) – go to 12.
____ Naturally, age (menopause) – go to 13.
____ Radiation or chemotherapy – go to 13.
____ Other (specify) – go to 13.
____ Doesn't know – go to 13.
____ Doesn't want to answer – go to 13.

12. When the surgery or hysterectomy was performed, how many of your ovaries were removed? (If the participant doesn't remember or doesn't understand the question you can say. GENERALLY WHEN BOTH OVARIES ARE REMOVED, THE DOCTOR PRESCRIBES HORMONES.)
____ **No** ovaries were removed, just the uterus was removed
____ Yes, 2 ovaries and the uterus were removed
____ Yes, 1 ovary and the uterus were removed
____ Doesn't know
____ Does not want to answer

{Interviewer: Use the illustrations of the different types of medications. Interviewer Manual page --}

13. Have you ever used estrogen, progesterone, or other feminine replacement hormones when you got menopause, during or after your change of life, or for menopause symptoms?

___No (0) **(go to question 14);**
___Don't know (9) **(go to question 14)**
___Yes (1) **(go to question 13a)**

13a. Are you taking hormones at this moment?

-----No (0) **(go to question 14);**
-----Don't know (9) **(go to question 14)**
-----Yes (1) **(go to question 13b)**

13b. Since when have you been taking hormones?

Month _____ Year _____
Don't remember ___ ……..99 9999

13c. How long did you take hormones?

Months……..… 1 (Specify how many months _____)
Years……..….. 2 (Specify how many years_____)
Don't remember ____…...….. 99 99

13d. What types of hormones have you used?

____ (1) Only estrogen……..…… (Specify the dose _____)
____ (2) Only progesterone....…….. (Specify the dose _____)
____ (3) Estrogen and progesterone...(Specify the dose _____)
____ (9) Don't know

14. Have you ever been pregnant? (Include any pregnancy, spontaneous abortion, ectopic pregnancy, abortions, etc.)

No (0) **(go to question 16)**; Yes (1)

14a. How many times have you been pregnant? ____ ____ Number of pregnancies

15. Please answer the following questions about each of your pregnancies.

	Pregnancy 1	Pregnancy 2	Pregnancy 3	Pregnancy 4
15a. How old were you when you had your first pregnancy ## age 99=Don't know				
15b. What was the outcome of the pregnancy? 1=Baby was born alive 2= Multiple babies 3= Baby was born dead (still born) 4=Spontaneous abortion**, go to next pregnancy** 5=Abortion**, go to next pregnancy** 6=Ectopic pregnancy**, go to next pregnancy** 9=Don't know, **go to next preganacy**				
15c. How many weeks did the pregnancy last for that one? ## (number of weeks). **If she doesn't remember ask:** 77=Premature (less than 9 months) 88=Completed term (9 months) 99=Don't know				
15d. How much weight did you gain during this pregnancy? ## (Enter the number of pounds she gained) **or,** 99=Don't know)				
15e Did you have nausea during this pregnancy? 1=No 2=Yes, during the first trimester 3= Yes, during the first 2 trimesters 4= Yes, during the all of the pregnancy 9=Don't know				
15f. Did you have gestational diabetes during this pregnancy? 1=No 2=Yes 9=Don't know				
15g Did you have high blood pressure or preeclampsia during your pregnancy? 1=No 2=Yes 9=Don't know				
15h What was the sex of this baby? 1=Male 2=Female 9=Don't know **(If the baby was stillborn, GO TO next pregnancy or to 16**.)				
15i Did you breast feed that baby? 1=No; (If No, go to next pregnancy or to 16) 2=Yes 9=Don't know				
15j For how many weeks did you breast feed the baby? ## weeks 99=Don't know				

15. (Cont.) Please answer the following questions about each of your pregnancies.

	Pregnancy 5	**Pregnancy 6**	**Pregnancy 7**	**Pregnancy 8**
15a. **How old were you when you had your first pregnancy?** ## age 99=Don't know				
15b. **What was the outcome of this pregnancy?** 1= Baby was born alive 2= Baby was born dead (still born) 3= Spontaneous abortion**, go to next pregnancy** 4= Abortion**, go to next pregnancy** 5= Ectopic pregnancy**, go to next pregnancy** 9=Don't know				
15c. **How many weeks did the pregnancy last for that one?** ## (Enter number of weeks.) **If they don't remember ask:** 77=Premature 88=Completed term 99=Don't know				
15d. How much weight did you gain during your pregnancy? ## (Enter the number of pounds she gained) or 99 =Don't know)				
15e Did you have nausea during your pregnancy? 1=No 2=Yes, during the first trimester 3= Yes, during the first 2 trimesters 4= Yes, during the all of the pregnancy 9=Don't know				
15f. Did you have gestational diabetes during your pregnancy? 1=No 2=Yes 9=Don't know				
15g Did you have high blood pressure or preeclampsia during your pregnancy? 1=No 2=Yes 9=Don't know				
15h What was the sex of this baby? 1=Male 2=Female 9=Don't know **(If he was stillborn, GO TO next pregnancy or to 16**.)				
15i Did you breast feed this baby? 1=No, **go to next pregnancy or to 16**) 2=Yes 9=Don't know				
15j For how many weeks did you breast feed this baby? ## weeks (Enter number of weeks.) 99=Don't know				

16. Have you ever had a mammography?
___No (0) **(Go to question 18)** ___Yes (1) ☐

17. a. What was the date of your last mammography? ☐
_____/_____/_____
(day) / (month) / (year)

b. Do you have the mammography you had within **the last year?** ☐
Yes ___ No____ Don't remember ____

Interviewer: Write in here the age of the participant (____) and use it to know when to finish question 18, that is, after getting to the age group of the participant

18. How much did you weigh when you were (____/Age)? If you were pregnant or breast feeding at that age, tell us how much you weighed a year before. For example, if you were pregnant or breast feeding a baby at age 20, then tell us how much you weighed when you were 19 years old.

18a. 20 years old Weight: _____ ___lbs. ___Kg. ___ Don't know

18b. 30 years old Weight: _____ ___lbs. ___Kg. ___ Don't know

18c. 40 years old Weight: _____ ___lbs. ___Kg. ___ Don't know

18d. 50 years old Weight: _____ ___lbs. ___Kg. ___ Don't know

18e. 60 years old Weight: _____ ___lbs. ___Kg. ___ Don't know

18f. 70 years old Weight: _____ ___lbs. ___Kg. ___ Don't know

19. How much did you weigh a year ago? ***(If the participant doesn't remember you can say 12 months ago; or during _____ a year ago on the same month of this interview***) If during this month you were pregnant or breast feeding your baby, how much did you weigh a year before being pregnant?

Weight: _____ ___lbs. ___Kg. ___ Don't know

Part III. Eating Habits. Write in the box the best indicator of the frequency of your food consumption.

Read to participant

In this section we're going to ask about your eating habits. PLEASE try to remember and answer as accurately as possible.

20. Please tell us about the food and the portions that you consumed in the past, this is during the last 12 months. **(The interviewer can help by providing exact date from this month, back to a year ago: for example, during 1 year ago, from July of last year]**. Indicate how many times you consumed the foods listed that we are going to read and if the portions were **S** (small), **M** (medium) or **L** (large) in comparison with the example illustrated.

Cereal	Portion			How many times you consumed 12 -24 MONTHS AGO?			
	S	M	L	Never Rarely	Each Month	Each Week	Each day
Cooked rice							
Cereal: cream of wheat, oatmeal, corn flour, corn starch							
Cold box cereals							
Soda crackers							
Whole wheat bread							
White bread							
Yellow tubers: yam, pumpkin, squash							
Other: potato, plantain, taro root, tanier root, breadfruit, prickly pear (veg)							
Pasta: spaghetti, elbows, etc.							

Vegetables	Portion			How many times you consumed 12 -24 MONTHS AGO?			
	S	M	L	Never Rarely	Each Month	Each Week	Each day
Corn							
Eggplant							
Peas							
Coleslaw							
Broccoli							
Cauliflower							
Beet							
Onion							
Green peppers							
Mushrooms							
Cucumber							
Tomato							
Mixed Vegetables							
Okra							
Celery sticks							
Asparagus							
Carrot							
Watercress							
Dark green lettuce							
Other lettuce							
Spinach							
Avocado							
Radish							
Beans: pink, red, white, black, lima, large white, chick peas, green beans, lentils							

Fruits	Portion			How many times you consumed 12 -24 MONTHS AGO?			
	S	M	L	Never Rarely	Each Month	Each Week	Each day
West Caribbean Cherry							
Apricot							
Cherry							
Orange, grapefruit, chironja, sweet lime							
Limes							
Prunes, dried prunes, raisins							
Fruit cocktail							
Strawberries							
Cranberries							
Soursop							
Guava							
Bananas							
Mango							
Apple, apple sauce, pear							
Peaches							
Melon							
Cantaloupe							
Papaya, Mamey							
Raisins							
Pineapple							
Quenepas, medlar							
Tamarind							
Grapes							

Dairy	Portion			How many times you consumed 12 -24 MONTHS AGO?			
	S	M	L	Never Rarely	Each Month	Each Week	Each day
Whole milk							
1% milk							
2% milk							
Yogurt							
Cheese							
White Cheese, Cottage cheese							

Drinks	Portion			How many times you consumed 12 MONTHS AGO?			
	<	=	>	Never Rarely	Each Month	Each Week	Each day
Black coffee		8oz					
Coffee with milk		4oz					
Hot tea		8oz					
Hot chocolate		8oz					
Soda		8oz					
Diet soda		8oz					
Natural juices		8oz					
Fruit juices: West Caribbean Cherry, passion fruit, tamarind, soursop, "mix Iced-tea"		12oz					
Maví (local root beer)		6oz					

Meats and substitutes	Portion			How many times you consumed 12 MONTHS AGO?			
	S	M	L	Never Rarely	Each Month	Each Week	Each day
Tofú							
Lunchmeat, Salami, bologna, ham, turkey							
Spam/ Deviled Ham, canned corned beef							
Sausage, Hot Dogs							
Chicken							
Turkey							
Pork							
Steak, ground beef							
Lamb							
Rabbit							
Goat							
White fish: Flounder, snapper, mero							
Salmon, tuna, mackerel							
Cod, herring, anchovy (salted/smoked)							
Sardines							
Shellfish: oysters, clams							
Lobster, shrimp							
Crab							
Trip							
Eggs							
Peanut butter							
Nuts, peanuts, almonds							

Desserts	Portion			How many times you consumed 12 -24 MONTHS AGO?			
	S	M	L	Never Rarely	Each Month	Each Week	Each day
Caramel custard							
Bread pudding							
Tembleque (coconut custard)							
Rice pudding							
Pie							
Extra sweet cake “Tres leches”							
Cookies							
Pastries (guava or cheese turnover, donuts							

Seasonings	Portion			How many times you consumed 12 -24 MONTHS AGO?			
	S	M	L	Never Rarely	Each Month	Each Week	Each day
Commercial salsa (sofrito)							
Homemade salsa (Sofrito)							
Garlic, onion							
Cilantro, wide leave cilantro, Chinese parsley							
Oregano							
Tomato sauce							
Cumin							
Olives							
Dried seasoning (Cube, “sazón”)							
Hot sauce							
Mustard							
Ketchup							

Others	Portion			How many times you consumed 12 – 24 MONTHS AGO?			
	S	M	L	Never Rarely	Each Month	Each Week	Each day
Meat pies							
Tanier/plantain and meat fritters							
Fried codfish dumplings							
Sweet plantain meat pie							
Potato meat pie							
Do you drink alcoholic beverages such as beer, wine, or mixed drinks? No ___ Yes:____ Drink of							

21 What do you use for frying food?

____ Vegetable oil ____ Butter

____ Lard ____ Margarine

____ Olive oil ____ PAM

22. What do you use to make the sofrito (homemade salsa) mix?

____ Vegetable oil ____ Butter

____ Lard ____ Margarine

____ Olive oil ____ PAM

23. In the last 12 -24 months, with what frequency did you go out to a restaurant, or fast food establishment to consume the following foods?

Type of fast food	**Portion**			**How many times you consumed 12 -24 MONTHS AGO?**			
	S	**M**	**L**	**Never Rarely**	**Each Month**	**Each Week**	**Each day**
Fried chicken							
Hamburger							
Pizza							
Chinese food							
Mexican food							
Fried fish							
Other							

Part IV. Exposure to Tobacco: <u>Read to participant</u>
I would like to ask you some QUESTIONS about YOUR SMOKING HABITS AND EXPOSURE TO TOBACCO or TO CIGARETTE SMOKE

24. Have you ever smoked cigarettes, pipe or cigar in your life? ☐
No (0) **(go to question 26)**; Yes (1); Don't know/Doesn't want to (9)
(go to question 26)

25. Have you smoked at least 100 cigarettes or 5 packs of cigarettes in your life? ☐
No (0) **(go to question 26)**; Yes (1); Don't know/Doesn't want to answer (9)
(go to question 26)

25a. At what age did you start smoking? _____ (age in years) ☐

25b. Do you smoke at this moment? ☐
No (0); Yes (1) **(go to question 26);** Don't know/Doesn't want to answer (9)

25c. Since when did you quit smoking? _____ (month/year) ☐

Part V. Physical Activity: Before beginning these questions on physical activity you must write down the age of the participant in the table where you will stop and not continue the interview.

Read to participant

In this section we will be asking you questions about your physical activity during some moments in your life. We can remember if we were very active or less active when we were children, adolescents or young adults because we can relate this to where we used to live, or the school we went to, or the tasks we did at home or at work during those years.

We would like to ask you to help us understand the type of physical activities that women in Puerto Rico do. For this reason we will ask you questions on physical activity that you were used to doing at six years old and at other moments of your life. PLEASE answer as accurately as you can remember. Think if these activities were done during the week, during the weekend, only during some days in particular o if they were daily activities. Also remember if you did these activities for a short time or for many hours during the week.

You can tell us about sports or exercise (such as lifting or moving heavy objects, aerobic exercise, swimming, etc.), or recreational activities (such as dancing, playing, riding bicycle, etc.) and about those activities related to daily living at home or workplace (such as sleeping, cleaning windows, mopping/wiping, cutting the lawn, picking up leaves, etc.). You can also tell us about the hours and minutes you spend walking or walked to school, work or to go shopping or visiting or how much time you spent as a way to exercise.

Age	**Type of physical activity** **(a) Vigorous physical activity** accelerates the heart a lot, you sweat a lot and it is difficult to talk because your breathing is accelerated. **(b) Moderate physical activity** increases the heart beat and breathing, you sweat a lot but you can talk while doing moderate activity.		**Frequency of physical activity** **0 = never** **1 =** <3 hrs./week **2 = 3 a 6 hrs.//week** **3 =** ≥7 hrs./ week
	Ask what type of physical activity and then if it was vigorous or moderate.	**a or b**	
26a. 6-11 years old (childhood)			
26b. 12-13 years old (pre-adolescence)			
26c. 14-22 years old (adolescence)			
26d. 23-50 years old (adult)			
26e. 51-64 years old			
26f. ≥65 years old			

27. In average, how many minutes per week do you walk _____ minutes

28. Please indicate which physical activity on this list you have done mostly during your life (Select all that apply) _____:

1) Sports
2) Activity related to work
3) Activity inside the house
4) Activity in the yard
5) Recreational

Part VI: Read to participant (Write down age of participant where you should finish the questions). In this section we will be asking questions on your exposure to the SUN.

29. In average, How much time do you spend outside, during the daylight hours, during the ages listed below. Give me your best estimate.

Age	Less than 30 minutes (1)	30 minutes or 2 hours (2)	More than 2 hours (3)
29a. 6-11 years old			
29b. 12-13 years old			
29c. 14-22 years old			
29d. 23-50 years old			
29e. 51-64 years old			
29f. 65 years old or more			

30. Do you have freckles in your back? Yes ____ , No ____, Don´t know _____

31. Do you burn easily while exposed to the sun in the afternoon?
Yes____, my skin turns red. No _____or Don't know _____, jump to 33

32. If you are repeatedly exposed to the sun, do your skin bronzes or get dark?
No _____, or Don't know _____
Yes ____, my skin gets **very dark**, dark bronze.
Yes ____, my skin gets **somewhat dark**.
Yes ____, my skin gets **light bronze, light brown**

33. When you were an adolescent, the drinking water came from…
1. Deep well ____
2. River ____
3. Surface well _____
4. Autoridad de Acueductos (AAA) _____

34. When you were an adolescent, was your house close to a ….
1. Gas station Yes ____ , No ____, Don't know _____
2. Pharmaceutical industry Yes ____ , No ____, Don't know _____
3. Other industries (textiles, electronics, etc.) Yes ____ , No ____, Don't know _____
4. Petroleum distilleries Yes ____ , No ____, Don't know _____
5. Sugar industry / refinery Yes ____ , No ____, Don't know _____
6. Waste dump Yes ____ , No ____, Don't know _____
7. Laundry, dry cleaners Yes ____ , No ____, Don't know _____
8. Paint and car repair shops Yes ____ , No ____, Don't know _____

Part VII. Personal and family history of chronic diseases

Read to participant:

Now I would like to ask you to tell me about the illnesses that you have had or have. PLEASE ANSWER AS ACCURATELY AS POSSIBLE.

35. Have **you been diagnosed** by a doctor with any of the following illnesses?

Diagnosed illnesses	**No (0)**	**Don't know (9)**	**Yes (1) →**	**Age when diagnosed**
35a. Diabetes (not during pregnancy)			Did you use insulin? ___yes ___no	
35b. High or elevated blood sugar or urine				
35c. Childhood asthma (before age 14)				
35d. Adult asthma (after age 14)				
35e. Ear or nasal allergies				
35f. Skin allergies				
35g. Benign breast illness (non cancerous): tumors, fiber-tumors, or mastitis				
35h. Skin cancer				
35i. **Any other type of cancer**, (not skin cancer), please describe: Breast CA (1) (Flag: inclusion criteria =case) Other cancer (2) (Flag: exclusion criteria =control)				
35j. Polycystic Ovarian disease				
35k. Thyroid illness (for example: hyperthyroidism, hypothyroidism).			__hyperactive __hypoactive	
35l. At any time have you received treatment for parasites?			___yes ___# of times	

36 Has anybody **in your family** been diagnosed by a doctor with any of the following illnesses? (include your parents, and if you have brothers, sisters or children)

Diagnosed Illness	**No (0)**	**Don't know (7)**	**Yes (1)**	
36a. Skin cancer			**Relationship**	**Age when diagnosed**
36b. any other type of cancer, that is not skin cancer:_____			**Relationship**	**Age when diagnosed**

Part VIII. Other demographic information

Read to participant:

Sometimes we need to contact participants to ask additional questions. We would like to know if you would give us information that may allow us to contact you.

37. What is your Social Security number? [*Interviewer: If there are doubtful, let them know that these questions will be kept confidential. If they don't want to answer skip this question*]

__ __ __ __ __ ___ ___ ___ ___

38. Please give us the name of a family member or friend, that doesn't live with you, that could help us contact you in the event we were unable to:

Name: _____

Address: _____

_____

Telephone number: Area Code (__) _____

Relationship: _____

Mother's last name: _____

Father's last name: _____

39a. It is helpful to have information about where your parents and grandparents were born. Can you tell us where your mother was born?_____

On your mother's side of the family:

Place of birth of your grandmother: _____

Place of birth of your grandfather: _____

394b. Can you tell us where your father was born?_____

On your father's side of the family:

Place of birth of your grandmother: _____

Place of birth of your grandfather: _____

Part IX. Read only to participant that has been diagnosed with breast cancer.

We are almost finished but you mentioned (in question 35i) that you had been diagnosed with a breast tumor or a mass. We will like to know about this and possible treatments or illness.

40. Have you made any changes in your regular diet as reported earlier, in the past two years?

_____ **Yes and the changes are the following (1)** _____**No (2)**

_____

_____

_____

_____

41. Have you made any changes in your consumption of supplements (vitamins, minerals) as you reported earlier, in the past two years?

____ **Yes and the changes are the following (1)** _____ **No (2)** ☐

_____

_____

_____

_____

42. Have you had any of the following treatments?

____ Breast biopsy
____ Mastectomy (Removal of all of the breast) (0)
____ Conservative breast surgery (Surgery without complete removal of breast, (Lumpectomy, partial mastectomy (1)
____ Breast implant
____ Breast remission surgery
____ Surgery in the lymph nodes under the arm
____ Radiation treatment for breast or chest
____ Chemotherapy
____ None of the above
____ Don't know/Not sure (7)
____ doesn't want to answer (9)

43. Are you taking or have taken tamoxifen? (Hormonal preventative therapy)

___ No (0)
___ Yes (1)
___ Took for some time, not taking now (3)
___ Thinking of taking; hasn't started yet (4)
___ Don't know/Not sure (7)
___ doesn't want to answer (9)

44. Are you taking or have taken aromatase inhibitors (i.e., Nolvadex)? [*Aromatase inhibitor is an enzyme that modifies the hormones and the inhibitors of the enzymes reduce the risk of cancer*]

___ No (0)
___ Yes (1)
___ Took for some time, not taking now (3)
___ Thinking of taking; hasn't started yet (4)
___ Don't know/Not sure (7)
___ doesn't want to answer (9)

Read to participant

THESE ARE ALL OF THE QUESTIONS FOR THIS SURVEY. THANK YOU FOR LETTING US INTERVIEW YOU. YOUR PARTICIPATION IN THIS STUDY IS OF GREAT HELP. THANKS AGAIN. (*Now say goodbye cordially and demonstrate your satisfaction with the cooperation of the participant*).

ONLY FOR INTERVIEWER

IN THIS SECTION DESCRIBE THE CONDITIONS OF THE INTERVIEW

1. Interview ended at: _____ a.m. _____ p.m.

2. Answer each one:

Question	YES	No
2a. Participant appeared to be alert through the interview	1	0
2b. Participant appeared to understand the questions	1	0
2c. Participant appeared to be tired during some point in the interview	1	0
2d. There were interruptions during the interview	1	0
2e. The length of the interview was 30 minutes, as expected	1	0

Imar Mansilla Rivera

Activities for the BCEPR

- Registered in a course on "Environmental Epidemiology", sponsored by the 2007 Summer Program in Applied Biostatistics & Epidemiological Methods, The Ohio State University, Columbus, Ohio. July 16-20, 2007
  Course description

  Environmental Epidemiology

  Harvey Checkoway, Ph.D., University of Washington

  This course will provide a summary of the epidemiologic study designs and methods for investigating health hazards associated with environmental exposures. Related topics that will be covered include: case cluster investigation methods; approaches to characterizing environmental exposures; sources of and methods to minimize study bias; and applications of epidemiologic data, such as for environmental risk assessment. Methodological concepts will be illustrated with examples of research on environmental risk factors for cancer, neurological diseases, respiratory diseases, and adverse reproductive outcomes. Lectures will be supplemented by discussions of selected journal articles and by in-class exercises that emphasize the roles public health practitioners play in the conduct of environmental epidemiology.

- Registered at the 19th Conference of the International Society for Environmental Epidemiology (ISEE), held in Mexico City, September 5 – 9, 2007.
  - Attended a pre-conference workshop on "Children's Vulnerability to Pollution"
  - Attended a training session on "Cancer susceptibility and environmental interactions"
  - Attended several oral and poster presentations on topics such as environmental exposures at different stages of development, health effects of various groups of contaminants (e.g. air pollutants, trace metals, persistent chlorinated and brominated compounds)
  - Presented a poster on "Arsenic exposure from fish consumption in Vieques, Puerto Rico", sponsored by the University of Puerto Rico-Roswell Park Cancer Institute Partnership (NIH/NCI P20 CA096257).

- Audited conferences on design and analysis of descriptive, cohort, case-control, and experimental studies, as well as confounding factors of epidemiologic studies in the course EPID 6523, Epidemiologic Methodology, September 12 – October 15, 2007.

- Registered in a short course titled Logistic Regression Modeling, held in San Juan, Puerto Rico, May 12 – 14, 2008.

- Registered in a short course titled "Effective Risk Communication: Theory, Tools for Practical Skills for Communicating about Risk", sponsored by Harvard School of Public Health, Boston, Massachusetts, from May 19 – 21, 2008.

- Registered at the Building Network Symposium and at the Era of Hope Meeting, held in Baltimore, Maryland, from June 24 – 28, 2008.

- Short course: "Logistic Regression Modeling in Epidemiologic Research" by Dr. Kleinbaum, May 12-14, 2008

- Building Networks Meeting Baltimore Maryland June 24-25th, 2008
- Breast Cancer Research Program Era of Hope Meeting, in Baltimore Maryland June 25-29th, 2008

Michele Schelske-Santos

Research

On January 31, 2008, Dr. Michelle Schelske Santos submitted an institutional grant proposal titled *Methodological development of vitamin D measures in human blood,* to the Seed Funds for New Areas of Investigation, Institutional Funds for Investigation grant program (*Fondos Institucionales Para Investigación, Fondos Semilla Para Áreas de Investigación Nuevas*) at the University of Puerto Rico, Rio Piedras Campus. The 2-year proposal would help develop the laboratory methodology needed to explore a potential protective factor against breast cancer in Puerto Rican women. Unfortunately, it was not funded.

Invited presentations

April 23, 2008, Dr. Michelle Schelske Santos was invited to give a conference from 9:30a.m. – 11:00a.m. titled, *Diet, Nutrition and Cancer Prevention,* to the employees of the Procurement Office, University of Puerto Rico, Rio Piedras, as part of the special activities scheduled for Administrative Assistant's Week (Secretary's Day).

Course curriculum and incorporation of technology

As part of the Biochemistry course (ECDO 4158) for undergraduate nutrition and dietetics students at the University of Puerto Rico, Rio Piedras Campus, Dr. Michelle Schelske Santos integrated an electronic discussion board (in Blackboard) on the subject of Diet, Nutrition and Cancer Prevention, in order for students to explore and dialog the biochemical and nutritional implications of traditional food and alternative nutrition therapies on cancer prevention.

Conferences/Training attended

April 12 – 16, 2008
San Diego Convention Center, San Diego, CA
2008 American Association for Cancer Research (AACR) Annual Meeting

April 12, 2008, pre-conference to the AACR meeting. Third World Institute for Cancer Research (WICR) Leadership Development Workshop: The Path of Women Who Lead, emphasizing characteristics, knowledge, skills and attitudes of effective female leaders in cancer research and careers.

June 24 – 25, 2008
Sheraton Baltimore City Center, Baltimore, MD
Congressionally Directed Medical Research Programs, Breast Cancer Research Program, Building Networks Symposium, Facilitating Progress to Eliminate Health Disparities

June 25 – 28, 2008
Baltimore Convention Center, Baltimore, MD

Department of Defense (DOD) Breast Cancer Research Program (BCRP) Era of Hope 2008 Meeting

Student Mentoring

Under the mentorship of Dr. Michelle Schelske Santos, two undergraduate students of the Nutrition and Dietetics Program, UPR-Rio Piedras, Jacqueline Martínez-Chaluisant and Dariana Soto-Reyes were accepted for and attended the 2008 Nutrition and Cancer Prevention Research Practicum sponsored by the Nutritional Science Research Group, National Cancer Institute, National Institutes of Health, and the Department of Nutrition at the Clinical Center, National Institutes of Health in Bethesda, Rockville, and Beltsville, MD, held March 17 – 21, 2008. These students competed at the national (USA) level with graduate students and interns, professionals in the health sciences, such as physicians and licensed dietitians; they were the only two undergraduates chosen for the cohort of 40 selected participants.

University at Buffalo
The State University of New York

Health Sciences Institutional Review Board &
Institutional Animal Care and Use Committee

March 31, 2008

Jo Freudenheim, PhD
Social and Preventive Medicine
University at Buffalo
270 Farber Hall
South Campus

TITLE: Breast Cancer Epidemiology in Puerto Rico - DOD
HSIRB # SPM1010308E

Dear Dr. Freudenheim:

The Health Sciences Institutional Review Board (HSIRB) by expedited review has considered and approved your initial submission for the protocol referenced above for a one-year period ending on **March 27, 2009**. The HSIRB approval includes:

- Complete protocol/grant
- Participant Control Sheet
- Participant Survey (2008)
- Consent form document

You are exempt from HIPAA requirements. The study does not involve the provision of health care and does not use any health information provided by a health care provider, health plan, or health care clearing house.

HSIRB approval is given with the understanding that no changes may be made in the procedures to be followed nor the consent form(s) to be used until such modifications have been submitted to the HSIRB for review and have been given approval.

Any unanticipated problems involving risk to human subjects and any serious adverse events must be reported promptly to the IRB.

Prior to the expiration of this approval, you will receive notification of the need for updated information to be used for the project's periodic review. Information concerning implementation, and results to date, will be required at that time. Studies cannot be conducted beyond expiration date without re-approval by the IRB.

Sincerely yours,

Darlene Campanella, CIP
HSIRB Chair Designee

Enclosure: Consent form document

DC/cb

Initial HIPAA exempt

University of Puerto Rico
Medical Sciences Campus
Graduate School of Public Health
P.O. Box 365067, San Juan, Puerto Rico 00936-5067

CONSENT TO PARTICIPATE IN RESEARCH

TITLE: **Breast Cancer Epidemiology in Puerto Rico**

SPONSOR: **Congressionally Directed Medical Research Program's Breast Cancer Research Program CDMRP #BC060131**

INVESTIGATORS: Cruz María Nazario-Delgado, Ph.D. (PI) University of Puerto Rico
Jo Freudenheim, PhD (Co-PI), University at Buffalo, Roswell Park Cancer Institute

This consent form may contain words that you do not understand. Please ask the study investigator or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about it or to discuss it with family or friends before making your decision.

I - INTRODUCTION

You have been invited to participate in a research study conducted at the University of Puerto Rico-Medical Sciences Campus. This project is funded by a grant from the Congressionally Directed Medical Research Program's Breast Cancer Research Program (BCRP) under the Historically Black Colleges and Universities/Minority Institutions Partnership Training Award mechanism. However, before you agree to take part in this study, please read this consent form carefully and ask as many questions as you need in order to be sure you understand the study procedures, including risks and benefits.

II - PURPOSE OF THE STUDY

We are conducting a project to examine how our diet and early life exposures are related to breast cancer. Other researchers have studied these factors in other populations. We want to examine the relation of these factors to cancer risk among women living in Puerto Rico. These include the different consumption patterns of legumes as well as other foods that are high in antioxidants. Researchers think that these foods are protective.

There are indications that exposures in early life, as early as pre-natal exposures, are important risk factors for breast cancer. It is thought that the breast tissue is more sensitive to environmental exposures while inside the mother's womb. Other researchers have discovered that birth weight, or having been breast fed is also related to breast cancer risk. Breast cancer risk could be related to childhood diet and body weight. We need to understand better how the infant, childhood and adolescent diet may be important protective factors from breast cancer. A study in our population will provide a better insight into the factors that protect or increase the risk of breast cancer n Puerto Rico.

III - STUDY PARTICIPANTS

In this study, 500 women aged 30-79, with newly diagnosed and confirmed breast cancer, who are residents of the San Juan Metropolitan catchment's area will be eligible to participate. Also, 500 women aged 30-79, without breast cancer, other than skin cancer, who are residents of the San Juan Metropolitan catchment's area will be eligible to participate. Pregnant women are not eligible to participate in this study because we will be collecting blood to study pathways such as hormones, nutrients and other bio-actives substances. Women less than 30 years or over 79 years of age, as well as those women that live in other geographical areas in Puerto Rico are not eligible to participate.

IV - PROCEDURES

If you agree to participate in the study, we need you consent for us to collect information through a questionnaire and to collect and process a fasting blood sample, about 3 tubes. If you can not give a blood sample, we can collect and process a saliva sample for the analysis. The procedure to collect the blood or the saliva sample is simple and the risk to your health is minimal. A trained research nurse at the Clinical Research Center, University of Puerto Rico, Medical Sciences Campus (CRC-UPR-MSC) will do this procedure. A nurse will measure your height, waist and weight. These are standard clinical procedures.

After these procedures and a snack, the study interviewer will ask you some questions. The interview will take approximately 30 minutes and the questions are related to your diet, physical activity, weight history, smoking, sun exposure, demographic characteristics, personal and familial history of chronic diseases, residential history, vitamin and medications use, menstrual and reproductive information as well as some questions about cancer diagnosis and treatment.

Once you have completed the interview your participation in the study will be over. The complete process should be over in less than 2 hours.

V - RISKS AND DISCOMFORTS

You understand that this study does not involve any new drug or clinical treatment. The procedure to collect the blood sample is simple and the risk to your health is minimal. This is a standard medical procedure. You understand that the blood will be draw while you are fasting and it will be done by a trained phlebotomist. Drawing blood from your arm may cause pain, bruising, lightheadness, and, on rare occasions, infection. If you feel any discomfort rest area will be available, and after the blood draw a snack will be provided.

You also understand that most questions in the questionnaire are not sensitive but there are a few questions that could be considerate as moderately sensitive (i.e., abortions). A professional woman with training in conducting public health studies will conduct the interview. Particular emphasis has been placed by training and supervision of the interviewer in order to minimize the potential risk during the administration of the questionnaire. You understand will be assured that you can refuse to answer any question that makes you uncomfortable without any negative consequence.

VI - BENEFITS TO SUBJECTS

You may not receive any personal benefits from being in this study. This study is not being done to improve your health. You have the right to refuse to participate in this study. Nevertheless, your participation in this study is very important because it will help us understand the factors that affect the risk of developing breast cancer among women living in Puerto Rico. The results of this study may improve our knowledge about how diet, physical activity, and hormone metabolism are related to breast cancer. Breast cancer is the most frequently diagnosed cancer among women in Puerto Rico. The number of women getting breast cancer continues to increase.

VII – COSTS There are no charges for the study visits.

VIII - COMPENSATION FOR PARTICIPATION

You will be paid $15 for your participation in the study after the questionnaire is completed to compensate for traveling expenses.

During this study, you will be asked to provide a blood sample. These samples will be used by investigators to look at inherited factors which are related to diseases by examining DNA and may also be used for purposes that are currently unknown. This DNA may be used for future analysis of genes that may regulate hormones, growth factors and other processes that may influence disease risk. There is a chance that the samples that you are donating under this study may be used in other research studies and may have some commercial value. Should your donated sample lead to the development of a commercial product, Dr. Cruz M. Nazario and Dr Jo Freudenheim will own it and may take action to patent and license the product. Drs Nazario and Freudenheim do not intend to provide me with any compensation for my participation in this study nor for any future value that the sample I have given may be found to have. I will not

receive any notice of future uses of my samples.

IX - ALTERNATIVES TO PARTICIPATE

This study does not involve medical treatment. You may refuse to answer any question in the questionnaire. Your refusal will not impact the treatment you may be receiving.

X - PRIVACY AND CONFIDENTIALITY

If you choose to be in this study, the investigator will get personal information about you. This may include information that might identify you. The investigator may also get information about your health using a questionnaire including: questions related to your diet, physical activity, weight history, smoking, sun exposure, demographic characteristics, personal and familial history of chronic diseases, residential history, vitamin and medications use, menstrual and reproductive information as well as some questions about cancer diagnosis and treatment. If you had a breast cancer diagnosis, the nurse will get information about the tumor.

Information about you and your health that might identify you may be given to others to carry out the research study. Data with your identifying information will be kept in a locked file cabinet and only authorized study personnel (PI, Project Coordinator, Lab technician and the clinical nurse) will have access to it. The information obtained in this study will be collected and sotred without personal identifiers and will be stored in password protected electronic data file. The records will be safeguarded as HIPAA regulations. The information may be reviewed by the UPR Medical Sciences Campus Institutional Review Board (UPR MSC IRB). The UPR MSC IRB is a group of people who perform independent review of research as required by regulations. Your personal health information will be kept as confidential as possible under the law. However, your personal health information is no longer protected by the privacy rule once it is disclosed to our associates, and may be shared with others. The results of this research may be published in scientific journals or presented at medical meetings, but no information will be included that will reveal your identity.

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel

this authorization at any time by sending a written notice to the principal investigator at the following address:

Dr. Cruz María Nazario
Biostatistics and Epidemiology Department
Graduate School of Public Health
Medical Sciences Campus, UPR
PO Box 365067 San Juan, PR, 00936-5067

If you cancel this authorization, the principal investigator will no longer use or disclose your personal health information under the authorization for this study, unless he/she needs to use or disclose some of your personal health information to preserve the scientific integrity of the study. Information submitted before you cancel this authorization can still be used by the associates.

The Authorization for Use and Disclosure of Protected Health Information for research purposes is completely voluntary. However, if you do not sign this document you will not be able to participate in this study.

XI – COMPENSATION FOR INJURY

In the event of physical and/or mental injury resulting from this research study, you will receive medical treatment free of change at the University Hospital or any other hospital designated by the Chancellor or the Medical Sciences Campus of the University of Puerto Rico. The University of Puerto Rico has no plans to provide any form of compensation directly to you. However, by signing this consent form you do not give up any legal rights.

XII – VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled. You can agree to donate blood or a saliva sample and to complete a questionnaire that collects personal information. If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without prejudice, any collected data will not be included in the study and blood will be discarded according to the laboratory procedure. The investigator may withdraw you from participating in this study if it is necessary. The decision may be made either to protect your health and safety by the investigator without your consent.

XIII – SOURCE OF FUNDING

This project is funded by the Congressionally Directed Medical Research Program's Breast

Cancer Research Program (BCRP) under the Historically Black Colleges and Universities/Minority Institutions Partnership Training Award mechanism.

XIV – QUESTIONS

If you have questions regarding this study or your participation in this study, or if at any time you feel you have experienced a research related injury, you may contact Dr Cruz M Nazario at this number: 787-758-2525 extension 1-1429 or Johan Hernández (Project Coordinator) at the 787-758-2525, extension 1-1964. If you have any questions about your rights as a research subject you may contact the

Human Research Subjects Protection Office
University of Puerto Rico
Medical Sciences Campus
Telephone 787-282-0018 or 787-282-0010
E-mail: opphi@rcm.upr.edu

Also, you can communicate with Dr. Cristina Nery, President of the Human Rights Committee of the Isaac González Martinez Oncology Hospital or with Dr. Hilda Rivera, Coordinator of Investigation of the Oncology Hospital at the phone 787-753-8433.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to be in this study, you will receive a signed and dated copy of this consent form with the stamp of the IRB approval for your records.

XV - CONSENT

I have read the information provided above or the information has been read to me). I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I freely consent to be in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

_____
Printed Name of Subject

_____ _____
Signature of Subject Date

_____
Printed name of Witness

_____ _____
Signature of Witness Date

_____ _____
Cruz Maria Nazario, PhD
Signature of Principal Investigator Date

Samples can be stored for future use
☐ Yes (Participant's initials, _____) ☐ No, samples can only be used in the current study.

Investigators may review my hospital or medical records
☐ Yes (Participant's initials, _____) ☐ No

Investigators may review my tumor tissue blocks
☐ Yes (Participant's initials, _____) ☐ No

University of Puerto Rico- Medical Science Campus
School of Public Health
Breast Cancer Epidemiology in Puerto Rico
Elegibility Verification Form

I. Eligibility Verification Form

Name: _____ Age: _____

Date of Birth: _____/_____/_____
(day) (month) (year)

Municipality ☐ San Juan ☐ Bayamón ☐ Carolina ☐ Toa Baja ☐ Guaynabo

☐ Toa Alta ☐ Caguas ☐ Other: _____

Cancer History: ☐ Yes ☐ No Cancer Type: _____

Pregnant: ☐ Yes ☐ No

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1. Eligible to participate in study: ☐ Yes ☐ No

II. Participation Confirmation

Wishes to participate in study ☐ Yes ☐ No

Indicate 3 days in which the participant would be willing to visit the Medical Science Campus Clinical Research Center (7:30am- 9:30am):

☐ Monday ☐ Tuesday ☐ Wednesday ☐ Thursday ☐ Friday

Other Options: _____

☐ Wishes to participate but does not wish to visit the Research Center

III. Contact Information

Telephone: (home) _____ (mobile) _____

Time of day at which we may contact you: _____

Address: _____
_____

Other address: _____
_____

The Epidemiology of Breast Cancer in Puerto Rico

Cruz M Nazario[1], Jo Freudenheim[2,3], Farah Ramírez[4], Imar Mansilla-Rivera[1], Michelle Schelske-Santos[4], Christine Ambrosone[3], Johan Hernández[1]: [1]University of Puerto Rico, Medical Sciences Campus at San Juan, [2]University of New York at Buffalo, Buffalo, NY, [3]Roswell Park Cancer Institute, Buffalo, NY and [4]University of Puerto Rico Río Piedras Campus, Río Piedras, Puerto Rico

ABSTRACT

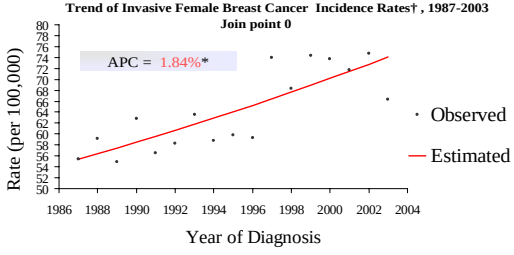
While breast cancer is the most commonly diagnosed cancer and the leading cause of cancer death among females in Puerto Rico (PR), rates of breast cancer are considerably lower than the rates in the continental US. At the same time, the rate of breast cancer has been climbing far more rapidly among Puerto Ricans than among women in the US. The reasons for these differences are not known but could be due to changing lifestyles, environmental exposures or genetic factors that differ from those in the mainland US. Exploration of breast cancer risk in a population with changing rates of disease is of particular interest because of greater variability in exposures, which may provide insight into disease risk for the better-studied populations where most, if not all, women have high exposures.

We are in the process of establishing a case control study of breast cancer in PR and a program to train breast cancer researchers in PR. The case control study will enroll women aged 30-79 who are residents of the San Juan metropolitan area. Cases will be women with incident, primary, pathologically confirmed breast cancer with no history of previous cancer other than non-melanoma skin cancer; controls will be frequency-matched on age and randomly selected from women residents of the same geographical area.

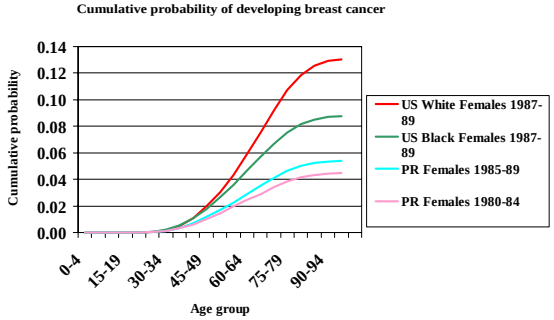
We will examine adult and childhood exposures in relation to risk of breast cancer in this understudied population of Puerto Rican women.

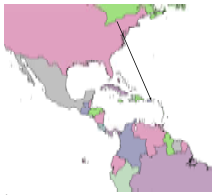
INTRODUCTION

Puerto Rico is a particularly interesting place for breast cancer research, because the incidence rate of breast cancer in Puerto Rico is about half that in the United States, but the risk of this disease among women in Puerto Rico is increasing at a faster rate than it is in the United States (Figures 1 & 2). The rapidly increasing rates are likely indicative of changes in the environment with resulting variability that could help us understand risk factors. In particular, there is likely to be more variation in early life exposures. Even though breast cancer rates are low in Puerto Rico a number of adverse risk factors are more common for women in Puerto Rico than in the United States. In the BRFSS, Puerto Rico has one of the highest prevalence of overweight and obesity, and lowest physical activity profiles. We want to study how these risk factors operate in this understudied Hispanic population of the United States. In addition, the racial mixture in the Puerto Rican population may provide an opportunity to better understand the observed differences in disease incidence and prognosis by race in the United States. Puerto Ricans have European, African, and Native American ancestry; the variation in racial admixture can generate greater variation, again allowing for the development of hypotheses that could lead to the elucidation of genetic risk factors and gene-environment interactions in future studies. Finally, there are aspects to the diet of Puerto Ricans that are of interest. These include different consumption patterns of legumes and other foods that are high in a variety of phytochemicals, including isoflavones and antioxidants. There are hypotheses that these foods are protective but to study them in most other US populations is difficult because consumption is low. Nevertheless, there have been few studies of breast cancer epidemiology in low risk populations.



† All rates are per 100,000 and age-adjusted to the 2000 PR population
*The Annual Percent Change (APC) is statistically significan from 0 (p value < 0.05)





METHODS

Our specific aims are:

To examine the following risk factors in relation to breast cancer and tumor characteristics:

1. Adult dietary risk factors. We hypothesize that factors associated with more traditional diet will be l common in cases than in controls. 2. More established risk factors in Puerto Rican population (e.g., lifetime weight gain, other dietary factors, physical activity, alcohol consumption, reproductive history). 3. Factors related to early life exposure including birth weight, adult height, childhood diet, physical activity environmental factors and residential history as a proxy for environmental exposure.

The overall training goal is to develop a team of independent investigators with the necessary skills to develop a program of breast cancer research in PR and to obtain funds and support for that research. To accomplish this goal, researchers from the UPR will obtain formal training in cancer epidemiology and participate in the design and conduct of the population-based case control study. Formal training will include coursework, workshops, and interactions with experts, and the primary collaborating mentor.

RESULTS

During the first year of the award, the University of Puerto Rico (minority institution) and the University at Buffalo (mentoring institution) have been in close communication to develop the study project, which includes in particular the study protocol, and the study questionnaire. This communication has included weekly teleconference calls of at least one hour, as well as frequent email communication. Dr Freudenheim visited the University of Puerto Rico to work with researchers on the questionnaire and to develop the study protocol. During that visit, Drs. Freudenheim, Nazario, Schelske-Santos and Mansilla-Rivera, with the assistance of the project coordinator, Johan Hernández, trained the study interviewer. There was considerable discussion on ways to reduce interview bias.

The study protocol was developed and submitted along with informed consent documents to the local IRB (UPR) and to mentoring institution's IRB (both the University at Buffalo and Roswell Park Cancer Institute (RPCI) where the sample storage and analysis will take place). Institutional Review Board approval was obtained from UPR, UB and RPCI. The questionnaire is being revised and a pilot interview has been scheduled to be conducted as soon as approval from funding agencies (CDMRP) is obtained.

Training of researchers from the University of Puerto Rico is an important objective of this project. Two of the investigators (Drs. Schelske-Santos and Mansilla-Rivera) from the minority institution participated in summer trainings. Dr. Schelske took a course in nutritional epidemiology at Johns Hopkins summer institute. Dr. Mansilla took a course in environmental epidemiology at Ohio State University. Drs. Schelske, Ramírez and Nazario attended the AACR meeting in April. Nazario, Schelske-Santos, and Hernández visited the University at Buffalo and Roswell Park Cancer Institute to meet with investigators regarding the implementation of the study protocol. In addition, laboratory personnel from RPCI (Lisa Carter) and from UPR (Nilda González) met to coordinate their activities regarding biological specimen collection, processing and long term storage.

FUTURE ACTIVITIES

Investigators will continue planning their training for the next several years. We are finalizing the questionnaire. We anticipate that with the IRB approval by the participating institutions, the funding agency will also approve the protocol allowing us to begin the case-control study. We also planning a meeting with the external advisory committee..

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